

REMARKS

The Election of Species Requirement

Regarding the comments on the Election of species, applicants wish to clarify that they did not argue “that the size of the particles is not relevant to the issue of obviousness.” Applicants stated that: “The size of one single particle is not relevant to the invention and would not be considered of relevance to one of ordinary skill in the art.” The election was made in terms of the size of a single particle and the relevance of this, as opposed to a particle size range, is not seen.

The Rejection under 35 U.S.C. §112

The rejection of claims 1-18, 21, 23, 35 and 36 under 35 U.S.C. §112, second paragraph, is respectfully traversed.

The TACE term and terms in claim 4 are well known terms of art and are use consistent with the known meaning in the art. The nature and scope of the claims is reasonably ascertainable by one of ordinary skill in the art, thus, the claim is not indefinite under 35 U.S.C. §112, second paragraph; see, e.g., Ex parte Porter, 25 USPQ2d 1144, 1146 (Bd. Pat. App. & Int. 1992), and Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385, 231 USPQ 81, 94-95 (Fed. Cir. 1986).

As to claim 12, the specification makes clear that the invention is directed to embodiments where the ingredients are separated prior to administration, e.g., in separate compartments of an inhaler (see, e.g., page 23, lines 22-24, page 25, line 1, and page 26, lines 10-11). Because it is made clear in the specification that the term “compositions” encompasses both of these types of embodiments, it is not indefinite to one of ordinary skill in the art reading the specification. Further, the use of the term composition in this manner is not completely repugnant to the meaning of the term. The ingredients are combined in some manner of proximity, thus, they can be considered a composition.

For the above reasons, the rejection under 35 U.S.C. §112 should be withdrawn.

The Rejection under 35 U.S.C. §103

The rejection of claims 1-5, 12-17, 35 and 36 under 35 U.S.C. §103 as being obvious over Disse (US 2002/0193394) in view of Trifilieff (Br.J.Pharmacol.) is respectfully

traversed.

The basis for rejection is that Disse teaches the use of tiotropium to treat COPD and asthma and Trifileff teaches the use of TACE inhibitors to treat COPD and asthma, therefore, it would have been obvious to combine them to obtain additive effects for use to treat COPD and asthma. It is admitted in the Office Action, however, that Disse provides no suggestion to use TACE inhibitors with tiotropium and that Trifileff provides no suggestion to use tiotropium with TACE inhibitors.

Applicants submit that no adequate motivation is provided by the references to make such combination. There are many type of compounds disclosed in the art as potentially useful for treating COPD or asthma. But there is no suggestion or reasoning why one of ordinary skill in the art would pick these particular two ingredients and combine them for such use. That the references merely exist in the same field of endeavor is not sufficient motivation to combine them. Motivation requires reasons provided in the art why one of ordinary skill in the art would combine the art-known elements; see, e.g., In re Rouffet, 149 F.3d 1350, 47 USPQ 2d 1453 (Fed. Cir. 1998).

Applicants also submit that the cited prior art does not provide a reasonable expectation of success that the combination would provide the alleged “additive effects” or even be useful for the stated purpose. In order to establish obviousness under 35 U.S.C. §103, the prior art must contain both a suggestion of the claimed method and provide a reasonable expectation of success for such method. See In re Vaeck, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991); and In re Dow Chemical Co., 5 USPQ2d 1529 (Fed. Cir. 1988). There is no basis to believe that the two ingredients would provide an additive effect, for instance – prior to applicants’ invention – it may have been just as reasonable to conclude that the ingredients could have an adverse effect on each other’s activity.

For the above reasons, it is urged that there is insufficient motivation to combine the references in the manner suggested in the Office Action. Thus, the rejection under 35 U.S.C. §103 should be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

No fee, other than the 2-Month Extension of Time being paid herewith, is believed to be due with this Amendment. However, the Commissioner is hereby authorized to charge

any additional fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

/John A. Sopp/
John A. Sopp, Reg. No. 33,103
Attorney for Applicant

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

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